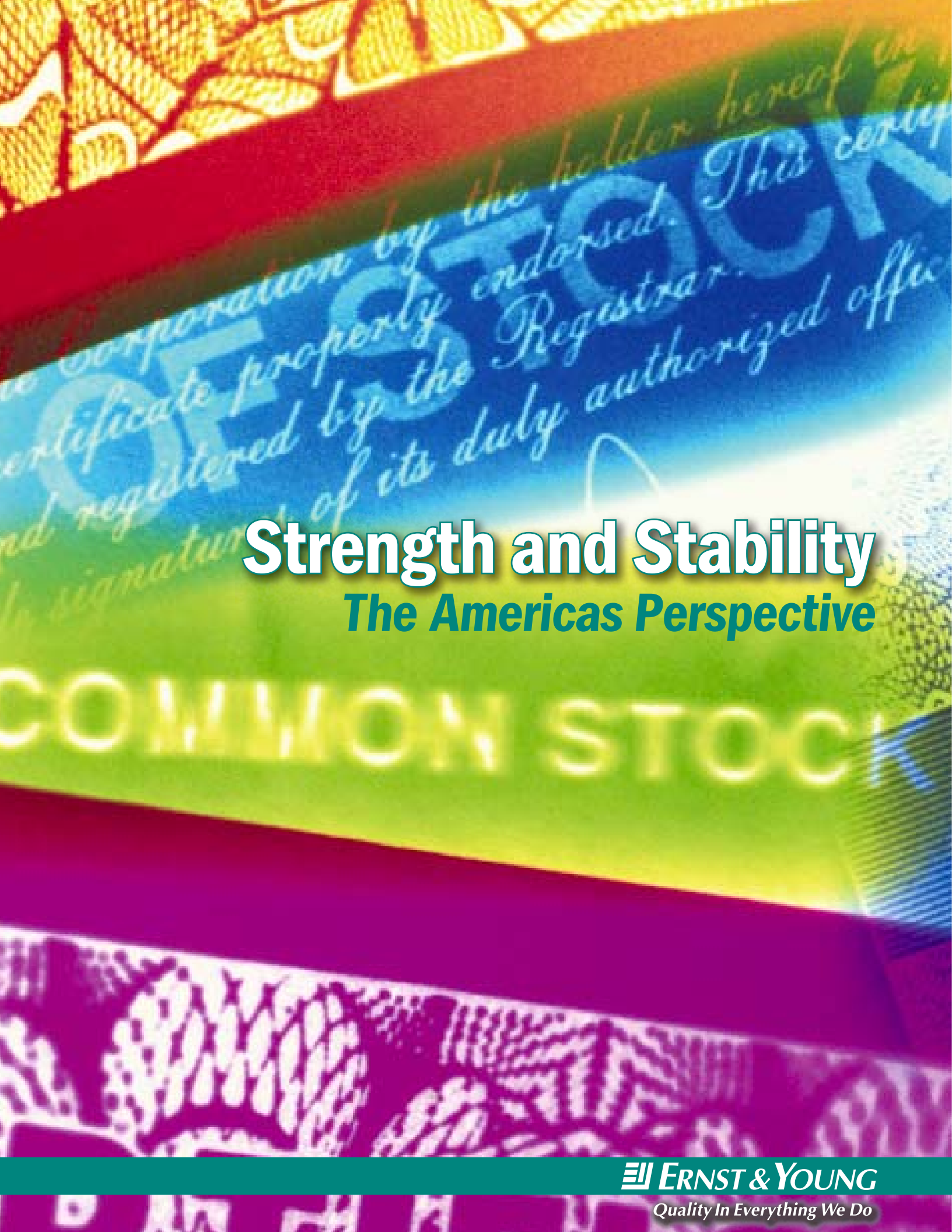
Strength and Stability
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Strength and Stability

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One year could have been a fluke, two a coincidence, but three is clearly a pattern. For the third consecutive year, the U.S. biotechnology sector has delivered strong product approvals and solid financial results. As the industry comes of age, investors are consistently focused on products and quality, flocking to companies with advanced pipelines. At the dawn of biotech's fourth decade, this appears to be the new reality. Say goodbye to fickle investor sentiment, initial public offering (IPO) windows, and boom-and-bust financing cycles. Say hello to steady product focus, stable financial results, and predictable valuations.

Continued stability

The stable performance of the last three years has its roots in the genomics bubble of 2000. The sky-high stock prices, booming IPOs, and sizeable financings of the 2000 bubble were an unprecedented event. But when the bubble burst, investors became risk averse and grew wary of companies that had immature pipelines and longer paths to products and profitability. Venture capitalists (VCs) were the first to make the shift, as the proportion of early-stage rounds declined.

After a significant gap, IPOs emerged in late 2003. In 2004, 28 U.S. companies went public, raising a total of $1.6 billion, roughly equal to the total amount raised in 2003, 2002, 2001, and 1999 *combined*. While it appeared to be a banner year for capital raised through IPOs, it soon became apparent that this IPO market was unlike the IPO windows of yesteryear. For decades, the industry's IPO windows—periods of wholesale enthusiasm for biotech stocks—had allowed a wide variety of companies to go public, including those with relatively immature pipelines. But after the bubble, only companies with late-stage pipelines and well-articulated paths to commercialization have received attractive valuations.

While this flight to quality increased the challenges for companies with less-advanced pipelines, it brought an unprecedented focus on commercialization. Firms scrambled to accelerate their product development efforts, restructuring their businesses and forming strategic alliances. These efforts began to pay off in 2003, when the U.S. industry saw a significant increase in product approvals.

The success on the product front inevitably improved financial performance, as stronger product sales boosted revenue. The healthier financial results, in turn, increased investor confidence in the sector, while also reinforcing investor appetite for advanced product development companies that could deliver near-term returns.

The industry's performance in 2005 demonstrates the sector's ability to sustain more stable, predictable, and stronger performance. The U.S. industry's revenues grew by about 16 percent—almost identical to its historical growth rate, and similar to growth in the last two years. Financing and product approvals were down compared to 2004, but still reflected the higher level of performance that the industry has sustained since 2003.

Since capital markets thrive on predictability, these developments bode well for continued growth. It might have been nice if the sector's performance on its 30th anniversary had broken records across every metric. But, in some ways, the 2005 results are more appropriate, and a better reflection of today's biotech industry. Through much of the industry's history, huge booms have been followed by sharp busts. The sector's ability to sustain consistent, stable growth represents real progress.

New challenges

While increased stability and predictability are good news for the biotech industry, the increased focus on late-stage products also has raised challenges for biotech companies in a couple of key areas.

The first challenge is reduced exit options. Since IPOs have been a traditional method for venture investors to exit their investments, the new IPO environment has made exit strategies more difficult for many companies. In essence, less mature firms relying on IPOs for exit events have two choices, neither of which is particularly attractive. They can accept lower valuations, which give them access to less capital and provide smaller returns for venture investors. Or they can choose to wait for key milestone events before going public, but achieving additional milestones almost always consumes substantial capital, making this option less attractive. This may give them the valuations they seek, but it would require them to survive longer on their existing capital. Also, this option may not be attractive to VCs who would have to delay their exits beyond their investment horizons.

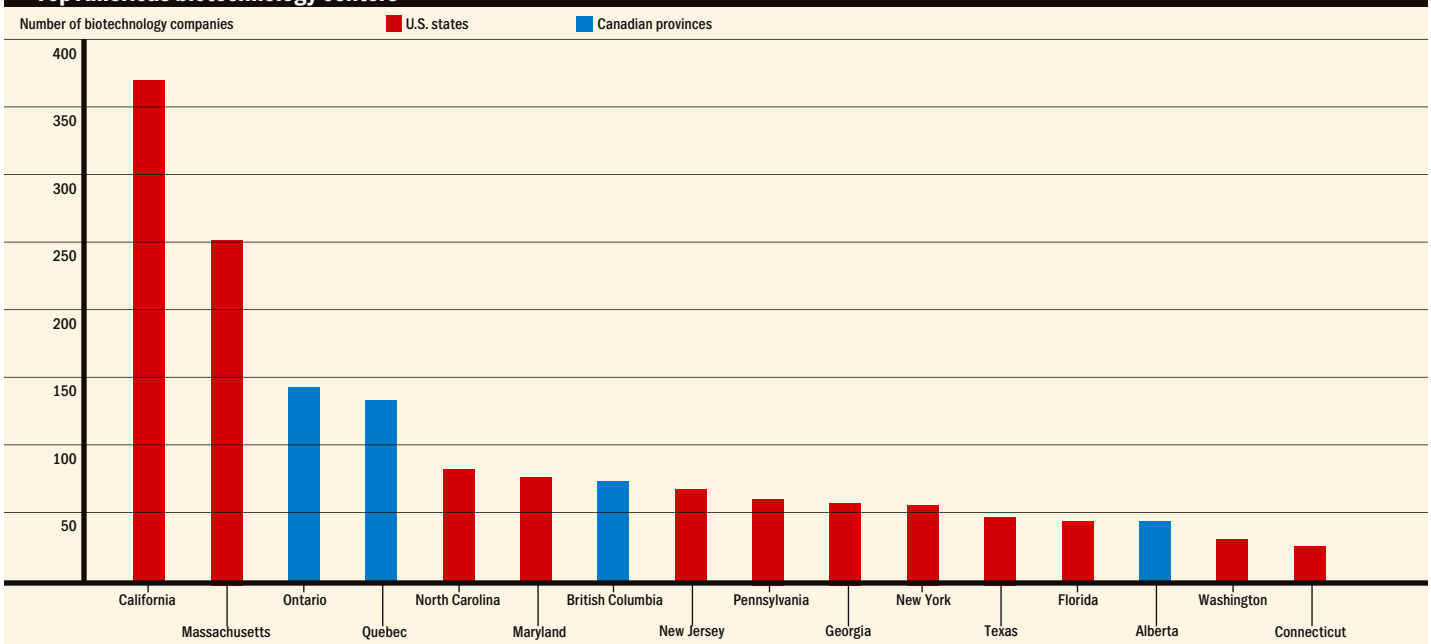
Not surprisingly, companies and investors have responded by moving to other exit strategies, notably mergers and acquisitions (M&As) and strategic alliances. For M&As, 2005 was a banner year, with a marked increase in pharma-biotech deals. While big pharma's pipeline challenges remain a key driver, biotech's need for exit options seems to be boosting the trend.

The second challenge resulting from the new investment environment is increased risk aversion. To some extent, this is a natural outcome of the industry's maturation. In biotech's early years, investors often had no choice but to back early-stage, high-risk companies. VCs were willing to take big bets, recognizing that with high risks came the potential for higher returns. Today's maturing biotech sector gives investors more options, allowing them to cherry-pick firms with advanced pipelines, lower downside risk, and the ability to provide near-term returns.

But if the maturation of the biotech industry is increasing options for investors, the sector's improving performance also is providing new choices for companies looking to raise capital. The investor base is broadening, as product approvals and healthy financials draw new investors to the sector. Biotech's reduced volatility is attracting hedge funds. Increasingly, large institutional investors are looking to the bigger biotech companies as viable alternatives to big pharma investments. Retail investors are starting to pay attention as well, raising the possibility of even wider across-the-board participation, but based on long-term value investing rather than speculation.

For the most part, these new investors are drawn to the sector's maturation and its high-visibility success stories. But the industry's continued growth will inevitably require investments in promising early-stage products and technologies. One potential solution, of course, is government funding, from sources such as the National Institutes

Top Americas biotechnology centers



Source: Ernst & Young
Data show number of public and private biotechnology companies by U.S. state or Canadian province

of Health (NIH), National Cancer Institute (NCI), and the Defense Advanced Research Projects Agency (DARPA).

But it is worth remembering that this industry was built on high-risk capital, and ultimately there is no substitute for experienced venture capital. As new investors focus on the bigger, established companies, seasoned VCs have the opportunity to go back to their roots—making early-stage, seed-round investments in companies with groundbreaking technologies.

Growing strength

The biotech industry's progress toward stability is a multiyear trend, and a story that is, almost by definition, relatively unchanged from the last two years. But 2005 also saw a significant new development—acceleration in the progress toward profitability. The net loss of U.S. publicly traded biotech companies fell by more than half, dropping from $4.9 billion in 2004 to $2.1 billion in 2005. While the industry's aggregate net loss has been lower at various points in the past, this represents the lowest net loss in relative terms. Net loss as a percentage of total revenue fell to 4 percent in 2005—the first time this ratio has dropped below the 5 percent threshold.

After three decades of red ink, it is certainly gratifying to see the industry edge closer to profitability. But it is also worth noting a truth often lost in discussions about industry profitability—the industry's historic net losses are overstated by the fact that some of its early success stories have been acquired over time by big pharma. If the profits generated by those companies were included, the sector may well have reached "profitability" years ago.

Also, while profitability is an important milestone, it is a somewhat symbolic one. The U.S. publicly traded biotech industry is not a single monolithic entity, but a collection of over 300 companies with a wide range of financial circumstances. For several years, the U.S. sector has had a core of profitable enterprises, and that number has not changed significantly over time. Instead, a stronger bottom line has been driven by significantly improved performances from the industry's most successful companies. Even with aggregate profitability, most U.S. biotech firms would still be in the red. Indeed, the fact that Australia beat the United States to the punch this year by achieving aggregate profitability in 2005 stems from the fact that Australia's company distribution is more skewed than that of the United States—which enables the strong results of CSL to swamp the unprofitable performance of a large number of smaller companies.

Sustainability

What long-term implications does this skewed distribution have for the industry's ability to sustain growth and deliver strong, stable financial results? The industry's uneven distribution is sometimes interpreted as a sign of its relative immaturity, based on the assumption that continued maturation will bring increased numbers of successful companies. But empirical experience from other industries suggests otherwise: Mature industries often are dominated by a small concentration of successful firms. It is certainly not clear that all of the industry's 300-plus public companies will—or should—become fully integrated Amgens and Genentechs in the near future.

For the industry's future development, companies must continue to bring new products to market, driving growth in sales and net income. It doesn't matter whether those successes come from many companies or a few. What is vital is that promising products currently trapped in struggling companies are allowed to come to fruition—increasing the importance of alliances or acquisitions. Consequently, for the industry's longer-term sustainability, it is critical for more companies to achieve profitability, or for increased consolidation to reduce the number of companies that are struggling to survive.

Current trends are moving companies in both directions. The emergence of significant biotech-biotech mergers in recent years is driving the trend toward increased consolidation, with Amgen's acquisition of Tularik and Abgenix as examples. Also, the challenging IPO market has prompted many firms to consider M&As as a preferred exit option. VCs and their portfolio companies are increasingly developing strategies that are designed from the outset to make themselves attractive acquisition targets.

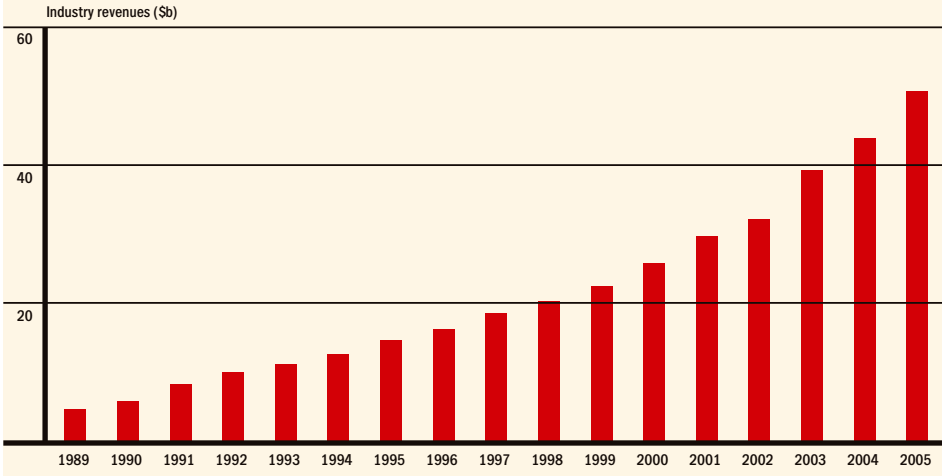
This is, of course, similar to the medical device market, a more mature sector that is dominated by a few big firms, supplemented by a large number of emerging companies that serve as a feeder system of sorts for the big companies. Small device companies often are engineered to fill a gap in the product portfolio of one of the larger firms. While the biotech industry is still far from achieving this structure, the medical device sector presents one scenario for a sustainable industry model based on an uneven distribution.

At the same time, emerging trends will broaden the base of profitable companies. The strong late-stage pipeline of the U.S. industry suggests that more companies will bring products to market for the first time, earning revenues and becoming profitable. In 2005, San Diego-based Amylin Pharmaceuticals achieved not one, but two first-time product approvals, and other companies with promising products in late-stage clinical trials likely will follow.

Even more significant is the emergence of targeted medicine approaches. The U.S. industry achieved several noteworthy product approvals in 2005 that are based on targeted approaches, and companies are increasingly basing their drug discovery strategies on these methods. Concerns about product safety and development costs are helping accelerate the transition. As targeted medicine challenges the blockbuster model, it will also have a democratizing effect on product development. With these approaches helping to reduce development costs and accelerate timelines, increasing numbers of smaller companies should be able to bring products to market and transition to profitability. Ultimately, this could lead to an even more profitable industry, and one whose success is based on a broader base of successful companies, building upon today's base of strength and stability.

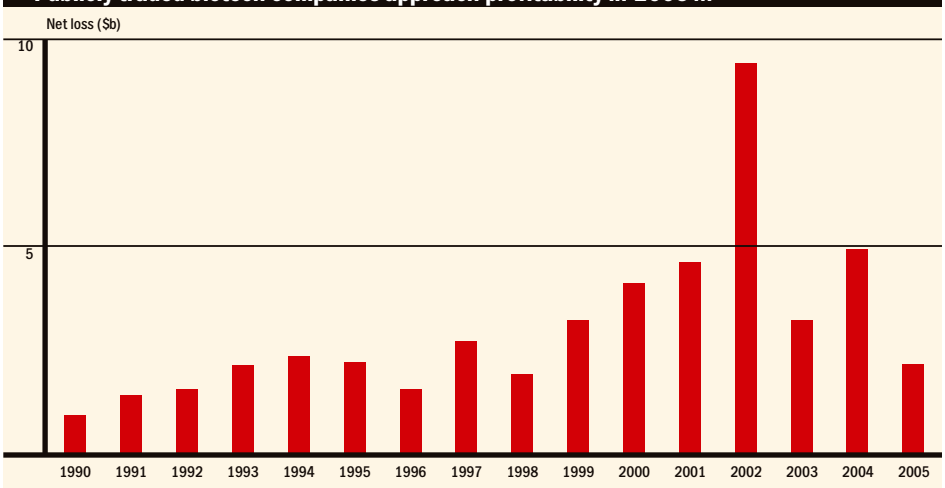
Path to profitability

U.S. public biotechnology industry revenues have grown at 16% CAGR since 1989



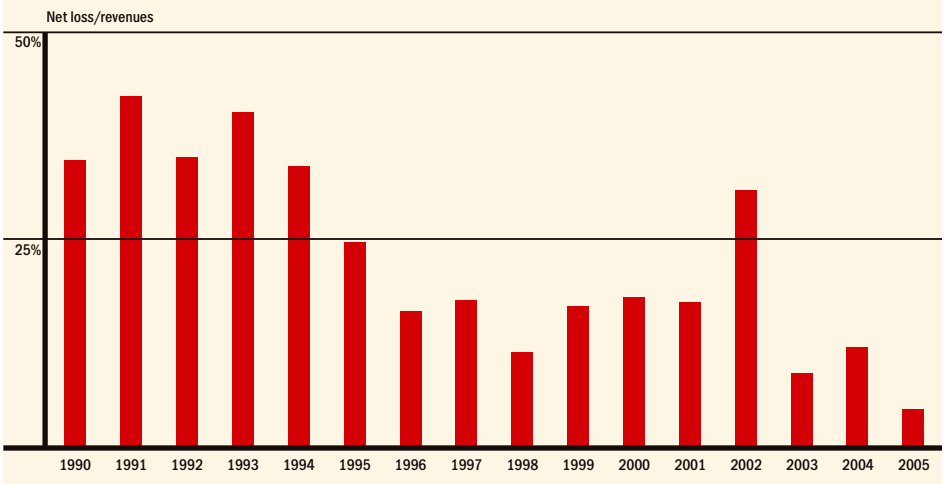
Source: Ernst & Young
Revenues of U.S. public and private biotechnology companies
CAGR: Compound Annual Growth Rate

Publicly traded biotech companies approach profitability in 2005 ...



Source: Ernst & Young

... as net loss relative to revenue reaches an historic low



Source: Ernst & Young

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